

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the declaration of the quantity of belladonna alkaloids (hyoscyamine sulfate, atropine sulfate, and hyoscyne hydrobromide) was false and misleading as applied to a product containing less than the declared amount of belladonna alkaloids, and the label declaration "NF" on some bottles, representing that the article was a drug, the name of which was recognized in the National Formulary, an official compendium, was false and misleading; 502(d)—the article in some bottles contained phenobarbital, a derivative of barbituric acid, and its label failed to bear the statement "Warning—May be habit forming"; 502(f) (1)—the labeling failed to bear adequate directions for use in that it was in dosage form in which it may be dispensed, and the label did not bear the common or usual dosage; and 503(b) (4)—the article in some bottles was a drug subject to the provisions of 503(b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11-1-61. Consent—claimed by Cambridge Pharmaceuticals and released under bond for reprocessing.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE*

6865. Various prescription drugs. (F.D.C. No. 46639. S. Nos. 13-148/55 T.)

QUANTITY: Approximately 300 boxes, btls., vials, etc., at Chicago, Ill., in possession of Jack's Drugs.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Sample," "Physician's Professional Package," "Professional Sample Not To Be Sold," "Professional Sample," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked by the dealer, Jack's Drugs, from physicians' samples into bottles to which had been affixed labels bearing the brand names of the drugs, a "complimentary—not for sale" professional sample legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois; some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, and bearing labels containing a "complimentary—not for sale" professional sample legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois; some of the articles had been on the premises when the drug store had been purchased by the dealer; and some of the articles had been obtained by the dealer from a local physician.

LIBELED: 11-13-61, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the words "Physician's Sample Not To Be Sold," "Physician's Sample," "Sample-Not To Be Sold," "Physician's Professional Package," "Professional Sample Not To Be Sold," "Professional Sample," and similar wording on the labels of the articles, were false and misleading as applied to the articles in the possession of a repacker and intended for sale, and not intended for use as "complimentary—not for sale"

*See also Nos. 6861, 6863, 6864.

samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labeling of the repacked articles failed to bear adequate directions for use and the articles were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug, as required by regulations.

DISPOSITION: 12-14-61. Default—destruction.

6866. Various prescription drugs. (F.D.C. No. 46583. S. Nos. 75/85 T.)

QUANTITY: 8,355 tablets and capsules and 204 containers of salves and liquids, and 1 227-tablet btl. labeled *Miluretic*, at Macclenny, Fla., in possession of Paul's Drug Store.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample," "Physician's Sample," "Sample: Not To Be Sold," "Clinical Trial Supply," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles which had not been repacked by the dealer consisted of quantities of prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, and bearing labels containing the words "Clinical Trial Supply," or similar wording, and the names of the manufacturers, packers, or distributors located outside the State of Florida. Some of the articles consisted of quantities of prescription drugs which had been repacked from physicians' samples into containers which had labels bearing the brand names of the drugs, a "complimentary—not for sale" professional sample legend, and the names of manufacturers, packers, or distributors located outside the State of Florida.

LBELED: 10-23-61, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the words "Professional Sample," "Physician's Sample," "Sample: Not To Be Sold," "Clinical Trial Supply," and similar wording on the labels of some of the articles, were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labeling of some of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drugs, as required by regulations; 501(d)(2)—tablets which were not *Miluretic tablets* had been substituted in part for *Miluretic tablets* in the 227-tablet btl. labeled "Miluretic"; and 502(a)—the name "Miluretic" on the label of one 227-tablet btl. was false and misleading in that such name represented that the article consisted entirely of *Miluretic tablets*, whereas the article did not consist entirely of such tablets but did consist in part of other tablets.

DISPOSITION: 11-27-61. Default—destruction.